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Tab 9
PREMARKET NOTIFICATION [510(k)] Summary

The CTS-7700 can be used for with Muscular-Skeletal Conventional and Superficial Superficial applications without any system or transducer modifications.

Nothing described in our previous submission, K061083 has been changed or modified for this submission.

All of the sections in this Tab 9 Premarket Notification [510(k)] Summary remain unchanged in this submission.

Tab 9
PREMARKET NOTIFICATION [510(k)] Summary

Trade Name:	CTS-7700 with C3L60B and L7L38B Transducers
Common Name:	Digital Ultrasound Imaging System
Classification Name:	Ultrasonic Pulsed Echo Imaging System, 90 IYO (per 21 CFR section 892.1560)
Manufacturer's Name:	Shantou Institute of Ultrasonic Instruments
Address:	#77, Jinsha Road, Shantou SEZ, 515041, China
Corresponding Official:	Li Delai
Title:	President
Telephone:	(86) 754-8250150 Fax: (86) 754-8251499
US Agent:	Bob Leiker/ Consultant /QRS 7263 Cronin Circle, Dublin, CA 94568 Telephone: 1-925-556-1302 Fax: 1-866-718-3819

Predicate Device: SonoAce 6000, K981510

Device Description:

The SIUI CTS-7700 is a digital diagnostic ultrasound system capable of the following operating modes: 2D (B mode) and B/M. The system is designed for use in linear and convex scanning modes and supports linear, and convex transducers. The system has cine review, image zoom, measurements and calculations, image storage and review, printing and recording capabilities. The system consists of probes, main unit, control panel and monitor.

Intended Use: Ultrasonic pulsed echo imaging and measurement for abdominal, pediatric, small organ, cardiac, peripheral vascular applications

Technological Characteristics:

1) Scanning modes: convex and linear scanning
2) Display modes:
   a) B-Mode (B, 2B)
   b) B/M-Mode
3) Supporting transducers:
   a) C3L60B: 2.5-5.0 MHz 60R 128e convex transducer
   b) L7L38B: 5.0-9.0 MHz 38mm 128e linear transducer
4) Focus mode:
   a) Transmit focus mode: 1-4 selectable, focus depth: variable
   b) Receive focus mode: dynamic focus
5) Grey scale: 256
6) Pre-processing:
   a) 32-channel digital beam-former;
   b) Receive gain (include TGC): 70dB
   c) Dynamic range: 35-66dB
   d) Edge enhancement: 4 steps
   e) Image persistence: 7 steps
   f) Line density: normal, high
7) Post-processing
   10 types of gray maps, among which 4 types are user-definable
8) Image manipulation:
   a) Real-time zoom in x4.0 max.
   b) Frozen image
9) B/M-mode speed:
   Time for full screen scroll: 1.2, 2.5, 5.0, 10.0 sec
10) Cine: Max. 256 frames
11) Image store and recall: 32 frames
12) Image orientation:
   a) Left/right flip
   b) Up/down flip
   c) 90-degree rotation (selectable steps: 0, 90, 180, 270 degrees)
13) Documentation and storage:
   a) 60GB HDD, images stored in BMP file format;
   b) USB interface memory, images stored in BMP file format
   c) Documentation devices:
   d) B&W video printer
   e) Parallel port printer (Inkjet or LaserJet)
14) Measurements and calculations
   a) General measurements and calculations
      2D: Distance, Area, Circumference, and Angle
      M-Mode: Distance, Time, Slope, Heart rate
   b) Specific measurements and calculations
      Abdomen, Obstetrics, Gynecology, Cardiology, Small parts, Peripheral Vascular

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Shantou Institute of Ultrasonic Instruments
% Mr. Bob Leiker
Consultant
QRS
7263 Cronin Circle
DUBLIN CA 94568

MAY - 2 2007

Re: K070982
Trade Name: CTS-7700
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: IYO and ITX
Dated: April 4, 2007
Received: April 6, 2007

Dear Mr. Leiker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the CTS-7700, as described in your premarket notification:

Transducer Model Number

Convex Array C3L60B
Linear Array L7L38B

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any

Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Ewa Czerska at (240) 276-3666.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Diagnostic Ultrasound Indications for Use Form

3.1 System Indications for Use Form

Device Name: CTS-7700

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Opthalmic										
Fetal		P							P	
Abdominal		P							P	
IntraOperative (Cardiac)										
IntraOperative Neurological										
Pediatric		P							P	
Small Organ (Specify)		P							P	
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Adult)										
Cardiac (Pediatric)		P							P	
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral Vascular		P							P	
Laparascopic										
Muscular-Skeletal Conventional		N							N	
Muscular-Skeletal Superficial		N							N	
Others (Specify)		P							P	

N = new indication P = previously cleared by FDA (K061083) E = added under Appendix E

Additional Comments: Small organs include: thyroid, testes, breast Combined: B/M Mode

Other uses include: Uterus, Ovary, and Prostate

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K070982

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

3.2 Transducer Indications for Use Form

Device Name: Convex Array C3L60B

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Opthalmic										
Fetal		P							P	
Abdominal		P							P	
IntraOperative (Cardiac)										
IntraOperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Adult)										
Cardiac (Pediatric)		P							P	
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral Vascular										
Laparascopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)		P							P	

N = new indication P = previously cleared by FDA (K061083) E = added under Appendix E

Additional Comments: Uterus, Ovary, and Prostate, Combined: B/M Mode

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070982

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

3.3 Transducer Indications for Use Form

Device Name: Linear Array L7L38B

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Opthalmic										
Fetal										
Abdominal										
IntraOperative (Cardiac)										
IntraOperative Neurological										
Pediatric		P							P	
Small Organ (Specify)		P							P	
Neonatal Cephalic										
Adult Cephalic										
Cardiac (Adult)										
Cardiac (Pediatric)										
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral Vascular		P							P	
Laparascopic										
Muscular-Skeletal Conventional		N							N	
Muscular-Skeletal Superficial		N							N	
Others (Specify)										

N = new indication P = previously cleared by FDA (K061083) E = added under Appendix E

Additional Comments: Small organs include: thyroid, testes, breast Combined: B/M Mode

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)

Division of Reproductive, **Abdominal,** and Radiological Devices

510(k) Number K070982

Prescription Use (Per 21 CFR 801.109)